

## Step Therapy Edit Criteria Proposal

Drug/Drug Class: **Antiplatelet Step Therapy Edit**

Prepared for: **Missouri Medicaid**  
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☐ New Criteria

☒ Revision of Existing Criteria

### Executive Summary

**Purpose:** Ensure that clopidogrel, ticlopidine, cilostazol, and aspirin/extended-release dipyridamole, are prescribed in patients with appropriate diagnoses and only after patients have tried aspirin, when suitable.

**Why was this Issue Selected:** Clopidogrel, ticlopidine, cilostazol, and aspirin/extended-release dipyridamole have shown to be as effective as aspirin in their antiplatelet effect. However, the cost of clopidogrel, and aspirin/extended-release dipyridamole is close to \$3 per day, ticlopidine is close to \$1.50 per day, while aspirin is \$0.02 per day.

Program-specific information:	Drug	Claims	Expense
	• Clopidogrel (Plavix)	92,773	\$10,324,773
	• Aspirin/dipyridamole ER (Aggrenox)	5,823	\$574,184
	• Cilostazol (Pletal)	11504	\$1,098,829
	• Ticlopidine (Ticlid)	1,921	\$86,888
	• Aspirin	78,846	\$850,434

04/02 - 03/03

**Setting & Population:** Prescribed in patients with history of stroke, myocardial infarction (MI), peripheral arterial disease, or unstable angina.

**Type of Criteria:**

<input type="checkbox"/> Increased risk of ADE	<input type="checkbox"/> Non-Preferred Agent
<input checked="" type="checkbox"/> Appropriate Indications	<input type="checkbox"/>

**Data Sources:** ☒ Only administrative databases ☐ Databases + Prescriber-supplied

## Setting & Population

- Drugs/drug classes for review:
  - clopidogrel (Plavix)
  - aspirin/extended-release dipyridamole (Aggrenox)
  - cilostazol (Pletal)
  - ticlopidine (Ticlid)
- Age range: all ages

## Approval Criteria <sup>1-5</sup>

- For patients currently on a nonpreferred agent (i.e., clopidogrel, aspirin/extended-release dipyridamole, ticlopidine, cilostazol) therapy will be approved if:
  - compliant with current nonpreferred therapy **OR**
  - a therapeutic failure to aspirin is identified (i.e., at least one aspirin claim in the last year) **OR**
  - a documented approval diagnosis or procedure as listed below (see approval diagnoses and approval procedures appendices)
- Clopidogrel (Plavix) -- Standard of Care (post-event)
  - Viable option for reducing overall risk of ischemic stroke or MI in patients who cannot tolerate or fail aspirin
  - Considered first line therapy in patients experiencing percutaneous coronary intervention (PCI) / percutaneous transluminal coronary angioplasty (PTCA) with or without stent, or CABG
    - Current practice guidelines recommend use as adjunctive therapy with aspirin to reduce incidence of subacute stent thrombosis in patients with successful coronary stent implantation
  - Only agent indicated for reduction of thrombotic events in peripheral artery disease or acute coronary syndrome
  - Considered first line therapy in patients experiencing unstable angina and non-ST-segment elevation myocardial infarction (UA/NSTEMI)
  - Used in patients who are at very high risk of a vascular event (MI, stroke, or established peripheral artery disease) or who have experienced a recurrent vascular event while taking aspirin.

Approval Diagnoses				
Condition	Submitted ICD-9 Diagnoses	Inferred Drugs	Date Range	Client Approval (Initials)
Myocardial infarction	410-410.92 Acute myocardial infarction 412 Old Myocardial Infarction	N/A	720 days	
Ischemic stroke*	435-435.9 Transient cerebral ischemia 437 Cerebral atherosclerosis 437.1 Acute cerebrovascular insufficiency; Chronic cerebral ischemia	N/A	720 days	
Established peripheral arterial disease	440.2-440.23 Atherosclerosis of native arteries of the extremities	N/A	720 days	
Acute coronary syndrome	411.1 Intermediate coronary syndrome (unstable angina) 410.7 Subendocardial infarction (non-Q-wave myocardial infarction)	N/A	720 days	
Diabetes	250.00	NA	2 years	
	NA	Antidiabetic agents	90 days	

\* Aspirin/extended-release dipyridamole use will not require an aspirin therapeutic failure in the treatment of ischemic stroke

Approval Procedures				
Condition	Submitted CPT Procedure Codes	Inferred Drugs	Date Range	Client Approval (Initials)
Coronary Artery Bypass Graft (CABG)	33510-33514 Coronary artery bypass, vein only 33517-33519, 33521-55323 Coronary artery bypass, using venous graft(s) and arterial graft(s) 33533-33536 Coronary artery bypass, using arterial graft(s)	N/A	270 days	
Percutaneous coronary intervention (with or without stent)	92973 Percutaneous transluminal coronary thrombectomy 92980-99281 Transcatheter placement of an intracoronary stent(s), percutaneous, with or without other therapeutic intervention, any method 92982, 92984 Percutaneous transluminal coronary balloon valvuloplasty 92986-92987, 99290 Percutaneous balloon valvuloplasty 92995-92998 Percutaneous transluminal coronary atherectomy, by mechanical or other method, with or without balloon angioplasty	N/A	270 days	

## Denial Criteria<sup>6</sup>

- Lack of evidence of aspirin therapy in patient's prescription claims history in the last year
- Absence of any of the approval diagnoses or procedures
- Clopidogrel
  - >75mg/day
  - Patients < 18 years of age
- Aspirin/extended-release dipyridamole, ticlopidine, cilostazol
  - > 2 tablets per day
  - Patients < 18 years of age

## Required Documentation

Laboratory results:


MedWatch form:

Progress notes:

Other:


## Disposition of Edit



- **Denial:** Exception 681 "Step Therapy"

## References

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2. Cairns JA, et al. Antithrombotic Agents in Coronary Artery Disease. Sixth American College of Chest Physicians (ACCP) Consensus Conference on Antithrombotic Therapy. Chest. 2001;119:228S-252S.
3. Jackson MR, Clagett GP. Antithrombotic Therapy in Peripheral Arterial Occlusive Disease. Sixth American College of Chest Physicians (ACCP) Consensus Conference on Antithrombotic Therapy. Chest. 2001;119:283S-299S.
4. Albers GW, et al. Antithrombotic and Thrombolytic Therapy for Ischemic Stroke. Sixth American College of Chest Physicians (ACCP) Consensus Conference on Antithrombotic Therapy. Chest. 2001;119:300S-320S.
5. The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. American Diabetes Association: Standards of Medical Care for Patients with Diabetes Mellitus. [Electronic version]. Diabetes Care 2003 Jan; 26 (1): S33-S50. Retrieved on May 29, 2003 from [http://care.diabetesjournals.org/content/vol26/suppl\\_1/](http://care.diabetesjournals.org/content/vol26/suppl_1/).
6. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2003
7. EBM Analysis: "Antiplatelet Therapy." University of Missouri Kansas City, Drug Information Center. October 2003.